

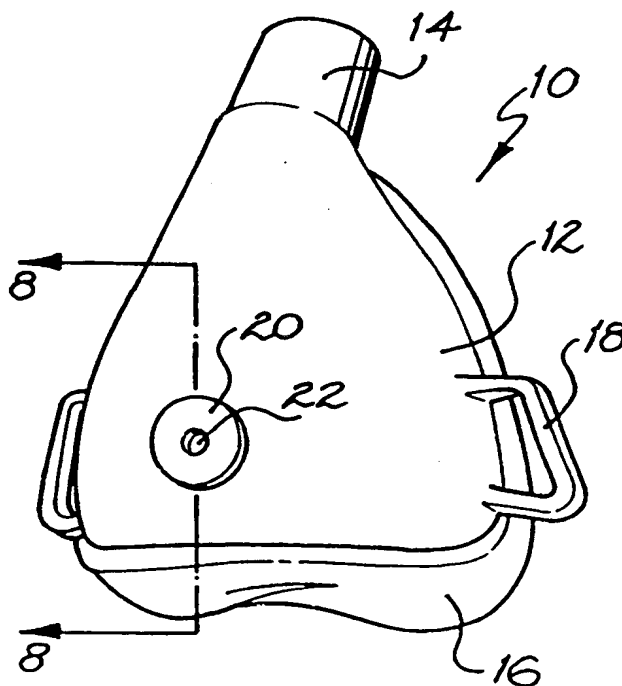


## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<b>(21) International Application Number:</b> PCT/AU98/00067 <b>(22) International Filing Date:</b> 6 February 1998 (06.02.98) <b>(30) Priority Data:</b> PO 5045                      10 February 1997 (10.02.97)                      AU <b>(71) Applicant (for all designated States except US):</b> RESMED LIMITED [AU/AU]; 82 Waterloo Road, North Ryde, NSW 2113 (AU). <b>(72) Inventor; and</b> <b>(75) Inventor/Applicant (for US only):</b> KWOK, Philip, Rodney [AU/AU]; 7 Apollo Avenue, West Pymble, NSW 2073 (AU). <b>(74) Agent:</b> SPRUSON & FERGUSON; G.P.O. Box 3898, Sydney, NSW 2001 (AU).		<b>(81) Designated States:</b> AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).  <b>Published</b> <i>With international search report.</i>

**(54) Title:** A MASK AND A VENT ASSEMBLY THEREFOR**(57) Abstract**

A mask (10) for use with a system for supplying breathable gas pressurised above atmospheric pressure to a human or animal's airways. The mask (10) includes a mask shell (12) which is, in use, in fluid communication with a gas supply conduit (30), and a gas washout vent assembly (20). At least the region of the mask shell (12) or conduit (30) surrounding or adjacent the vent assembly is formed from a relatively flexible elastomeric material.



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## A MASK AND A VENT ASSEMBLY THEREFOR

### FIELD OF THE INVENTION

The present invention relates to a mask and a vent assembly therefor.

5       The mask and vent assembly according to the invention have been developed primarily for the venting of washout gas in the application of continuous positive airway pressure (CPAP) treatment in conjunction with a system for supplying breathable gas pressurised above atmospheric pressure to a human or animal. Such a system is used, for example, in the treatment of obstructive sleep apnea (OSA) and  
10       similar sleep disordered breathing conditions. However, the invention is also suitable for other purposes including, for example, the application of assisted ventilation or respiration.

The term "mask" is herein intended to include face masks, nose masks, mouth masks, nasal pillows, appendages in the vicinity of any of these devices and the like.

15

### BACKGROUND OF THE INVENTION

Treatment of OSA by CPAP flow generator systems involves the continuous delivery of air (or other breathable gas) pressurised above atmospheric pressure to a patient's airways via a conduit and a mask.

20       For either the treatment of OSA or the application of assisted ventilation, the pressure of the gas delivered to a patient can be at a constant level, bi-level (ie. in synchronism with patient inspiration and expiration) or autsetting in level to match therapeutic need. Throughout this specification the reference to CPAP is intended to incorporate a reference to any one of, or combinations of, these forms of pressure  
25       delivery.

The masks used in CPAP treatment generally include a vent for washout of the gas to atmosphere. The vent is normally located in the mask or in the gas delivery conduit adjacent the mask. The washout of gas through the vent is essential for removal of exhaled gases from the breathing circuit to prevent carbon dioxide "re-

breathing" or build-up, both of which represent a health risk to the mask wearer. Adequate gas washout is achieved by selecting a vent size and configuration that will allow a minimum safe gas flow at the lowest operating CPAP pressure, which, typically can be as low as around 4 cm H<sub>2</sub>O for adults and 2 cm H<sub>2</sub>O in paediatric applications.

5 Prior art masks are generally comprised of a rigid plastic shell which covers the wearer's nose and/or mouth. A flexible or resilient rim (or cushion) is attached to the periphery of the shell which abuts and seals against the wearer's face to provide a gas-tight seal around the nose and/or mouth.

A prior art washout vent utilized one or more holes or slits in the rigid shell or  
10 in a rigid portion of the delivery conduit to allow the washout gas to vent to atmosphere. In some masks, the holes or slits were formed during the moulding process. In others, they were drilled or cut as a separate step after the shell or conduit had been moulded.

The flow of gas out the holes or slits in the shell or conduit to atmosphere  
15 creates noise and turbulence at the hole or slit outlet as the delivered gas, and upon expiration, the patient-expired gas (including CO<sub>2</sub>) exits. Bi-level and autosetting gas delivery regimes tend to generate more noise than a constant level gas delivery regime. This is thought to be due to the extra turbulence created by the gas accelerating and decelerating as it cycles between relatively low and relatively high pressures. The  
20 noise adversely affects patient and bed-partner comfort.

Another prior art vent included hollow rivets or plugs manufactured from stainless steel or other rigid materials attached to openings in the rigid shell. The outer edges of the rivets were rounded to help reduce noise. However, this approach was expensive, required an extra production step and did not prove effective in reducing  
25 noise.

Another approach to reduce noise involved the use of sintered filters at the gas outlet of the mask shell. However, the filters were prone to blocking, especially in the presence of moisture. Accordingly, sintered filters were impractical for use in CPAP treatment as they were easily blocked by the moisture from the patient's respiratory

system or humidifiers or during the necessary regular cleaning of the mask and associated componentry.

Foam filters wrapped around the air outlets in the shell were also attempted. However, they also suffered from the disadvantages of being prone to blocking,  
5 difficult to clean and requiring constant replacement.

Remote outlet tubes have been used to distance the noise source from the patient. However, these tubes are difficult to clean, are prone to entanglement by the patient and/or their bed partner and suffer the further disadvantage that a volume of exhausted gas is retained in the tube adjacent the mask.

10 It is an object of the present invention to substantially overcome or at least ameliorate the prior art disadvantages and, in particular, to reduce the noise generated by gas washout through a mask.

#### SUMMARY OF THE INVENTION

15 Accordingly, the invention, in a first aspect, discloses a mask for use with a system for supplying breathable gas pressurised above atmospheric pressure to a human or animal's airways, the mask includes a mask shell which is, in use, in fluid communication with a gas supply conduit, a gas washout vent assembly, wherein at least the region of the mask shell or conduit surrounding or adjacent the vent assembly  
20 is formed from a relatively flexible elastomeric material.

In an embodiment, the entire mask is formed from the elastomeric material.

In another embodiment, the mask shell and/or conduit is formed from a relatively rigid material and the region surrounding or adjacent the vent assembly is formed from the relatively flexible elastomeric material.

25 In a second aspect, the invention discloses a vent assembly for the washout of gas from a mask or conduit used with a system for supplying breathable gas pressurized above atmospheric pressure to a human or animal, wherein the vent assembly is formed from the relatively flexible elastomeric material.

In a preferred embodiment, the vent assembly is an insert of relatively flexible elastomeric material, wherein the insert is attachable to the mask shell or conduit. The insert preferably has at least one orifice therethrough.

In a preferred form, the rigid plastics mask shell is formed from polycarbonate  
5 and the insert is formed from Silastic™ or Santoprene™.

Desirably, the insert is substantially crescent-shaped and includes a plurality of orifices therethrough.

The insert preferably includes a groove around its periphery, the groove adapted to locate the insert against a correspondingly sized rim of an opening formed in  
10 the mask shell or conduit.

In other embodiments, the insert is substantially circular, triangular, cross or peanut shaped.

The mask shell and/or the conduit can desirably also include one or more inserts.

15

## BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the invention will now be described, by way of examples only, with reference to the accompanying drawings in which:

- Fig. 1 is a perspective view of a first embodiment;  
20 Fig. 2 is a perspective view of a second embodiment;  
Fig. 3 is a perspective view of a third embodiment;  
Fig. 4 is a perspective view of a fourth embodiment;  
Fig. 5 is a perspective view of a fifth embodiment;  
Fig. 6 is a perspective view of a sixth embodiment;  
25 Fig. 7 is a perspective view of a seventh embodiment;  
Fig. 8 is a partial cross-sectional view of the first embodiment along the line 8-8 of Fig. 1;  
Fig. 9 is a perspective view of an eighth embodiment;  
Fig. 10 is a plan view of the insert of the third embodiment;

Fig. 11 is a cross-sectional view of the third embodiment insert along the line 11-11 of Fig. 10; and

Fig. 12 is a partial cross-sectional view of the third embodiment insert along the line 12-12 of Fig. 10.

5

## DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring firstly to Fig. 1, there is shown a mask 10 for use with a system (not shown) for supplying breathable gas pressurised above atmospheric pressure to a human or animal's airways. The mask includes a rigid plastics shell 12 having an inlet tube 14  
10 for connection to a supply conduit to communicate breathable gas from a flow generator (not shown) to the nasal passages of the mask wearer. The mask shell 12 also includes a flexible sealing membrane 16 which is used to provide a gas tight seal between the face of the wearer and the interior of the shell 12. The shell 12 also includes lugs 18 for connecting the mask 10 to a head strap (not shown) to retain the mask in place.

15 The mask includes a Silastic™ insert 20 through which is provided an orifice 22 for gas washout. As best shown in Figure 8, the insert 20 has a recess or groove 24 around its periphery. A correspondingly sized opening 26 bounded by a rim 28 is provided in the shell 12 to enable the insert 20 to be retained in place in the fashion of a grommet. The opening 26 can be moulded in the shell 12 or drilled or punched as a  
20 post-moulding step. The flexibility of the Silastic™ allows the insert 20 to be initially squeezed through the opening 26 before resiliently expanding to the configuration shown in Fig. 8 and engaging the rim 28.

Figs. 2 to 7 show further embodiments in which corresponding reference numerals are used to indicate like features. In all these embodiments the insert 20 has  
25 an external groove or recess 24 which engages the rim 28 of a corresponding shaped opening 26 in the mask shell 12 to retain the insert 20 in place.

In the embodiment shown in Figs. 2 to 5 and 7 the insert 20 includes more than one orifice 22. In the embodiment shown in Fig. 6, two inserts 20 are provided in the shell 12.

In the embodiment shown in Fig. 9, the insert 20 is provided in a gas supply conduit 30.

Figs. 10 to 12 show the insert 20 of the third embodiment of Fig. 3. The dimensions 32, 34, 36, 38, 40, 42 and 44 are approximately diameter 1.73 mm, diameter 3.30 mm, 28.80 mm, 19.00 mm, 1.20 mm, 1.20 mm and 3.60 mm respectively.

The side 44 of the insert 20 faces the patient's face in use and the side 46 faces atmosphere.

The mask shell 12 is manufactured from polycarbonate. Other rigid plastics materials can equally be used. The insert 20 can be manufactured from an elastomer sold as Silastic™ (produced by the Dow Corning Corporation) or a thermoplastic elastomer sold as Santoprene™ (produced by Monsanto). Other flexible elastomeric materials can be used also.

The mask 10 produces less noise than an identical mask having a similar sized and shaped orifice(s) formed directly in the mask shell 12 instead of formed in the flexible insert 20. It is thought that the noise reduction occurs due to the flexible insert 20 damping vibrations caused by air passage through the orifice(s) 22 which produce vibrations or similar in the mask shell 12.

A prototype of the embodiment of the invention shown in Figure 3 has been tested over a range of constant and bi-level CPAP treatment pressures. For comparison purposes, an identical mask to that shown in Fig. 3 but formed entirely from polycarbonate and having six identical arcuately spaced holes 22 drilled directly through the mask shell was also tested. In both masks the six holes had a diameter of 1.7 mm. The results of the test are summarised in the Tables below:



**TABLE 1**Constant level gas delivery

Pressure (cm H <sub>2</sub> O)	Noise levels 1m from mask (dBA)	
	With flexible insert	Without flexible insert
4	26.8	35.2
10	33.4	43.1
18	39.3	49.2

5

**TABLE 2**Bi-level gas delivery

Pressure (cm H <sub>2</sub> O)	Noise levels 1m from mask (dBA)	
	With flexible insert	Without flexible insert
5 - 10	30.8 - 38.5	37.2 - 43.0
10 - 15	38.6 - 43.7	42.9 - 47.9

As the results show, the mask shown in Figure 3 produced less radiated noise  
 10 than a similar mask not including the flexible elastomeric insert 20 representing a  
 significant advantage in terms of the comfort of the mask wearer and their bed partner.

In addition to the noise reduction discussed above, the masks 10 possesses  
 other advantages over those of the prior art. Firstly, the insert 20 is very easy to install  
 into the mask shell 12 during either assembly of the mask which, is often supplied in kit  
 15 form, or before and after cleaning which is regularly required and often carried out in  
 the home environment. Secondly, the mask shell 12 may be produced with a single

size of opening 26 and provided with a range of different inserts 20 which allows the outlet size to be "tuned" to give an optimum gas washout rate for a particular patient's treatment pressure level.

Although the invention has been described with reference to specific examples,  
s it will be appreciated by those skilled in the art, that the invention may be embodied in many other forms.

## CLAIMS

1. A mask for use with a system for supplying breathable gas pressurised above atmospheric pressure to a human or animal's airways, the mask includes a mask shell which is, in use, in fluid communication with a gas supply conduit, and a gas  
5 washout vent assembly, wherein at least the region of the mask shell or conduit surrounding or adjacent the vent assembly is formed from a relatively flexible elastomeric material.
2. A mask as claimed in claim 1, wherein the entire mask is formed from the elastomeric material.
- 10 3. A mask as claimed in claim 1, wherein the mask shell and/or conduit is formed from a relatively rigid material and the region surrounding or adjacent the vent assembly is formed from the relatively flexible elastomeric material.
4. A mask as claimed in claim 1 or 3, wherein the vent assembly is an insert of relatively flexible elastomeric material and is attachable to the mask shell or  
15 conduit.
5. A mask as claimed in claim 1, 3 or 4, wherein the insert has at least one orifice therethrough.
6. A mask as claimed in any one of claims 1 or 3 to 5, wherein the rigid plastics mask shell is formed from polycarbonate and the insert is formed from  
20 Silastic™ or Santoprene™.
7. A mask as claimed in any one of claims 1 or 3 to 6, wherein the insert is substantially crescent-shaped and includes a plurality of orifices therethrough.
8. A mask as claimed in any one of claims 1 or 3 to 7, wherein the insert includes a groove around its periphery, the groove adapted to locate the insert against a  
25 correspondingly sized rim of an opening formed in the mask shell or conduit.
9. A mask as claimed in any one of claims 1 or 3 to 8, wherein the insert is substantially circular, triangular, cross or peanut shaped.
10. A mask as claimed in any one of claims 4 to 9, wherein the mask shell or the conduit includes a plurality of said inserts.

11. A vent assembly for the washout of gas from a mask or conduit used with a system for supplying breathable gas pressurized above atmospheric pressure to a human or animal, wherein the vent assembly is formed from a relatively flexible elastomeric material.

5 12. A vent assembly as claimed in claim 11, wherein the vent assembly is an insert of relatively flexible elastomeric material and is attachable to the mask shell or conduit.

13. A vent assembly as claimed in claim 11 or 12, wherein the insert has at least one orifice therethrough.

10 14. A vent assembly as claimed in claim 11, 12 or 13, wherein the rigid plastics mask shell is formed from polycarbonate and the insert is formed from Silastic™ or Santoprene™.

15. A vent assembly as claimed in any one of claims 11 to 14, wherein the insert is substantially crescent-shaped and includes a plurality of orifices therethrough.

15 16. A vent assembly as claimed in any one of claims 11 to 15, wherein the insert includes a groove around its periphery, the groove adapted to locate the insert against a correspondingly sized rim of an opening formed in the mask shell or conduit.

17. A vent assembly as claimed in any one of claims 11 to 16, wherein the insert is substantially circular, triangular, cross or peanut shaped.

20

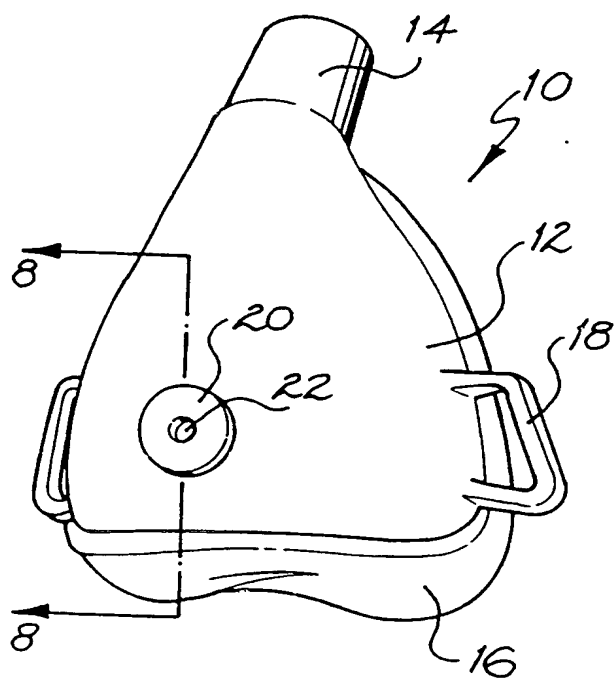


FIG. 1

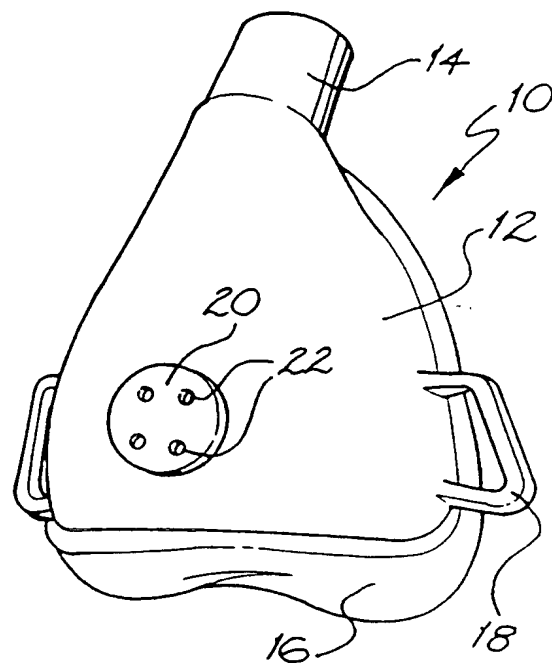


FIG. 2

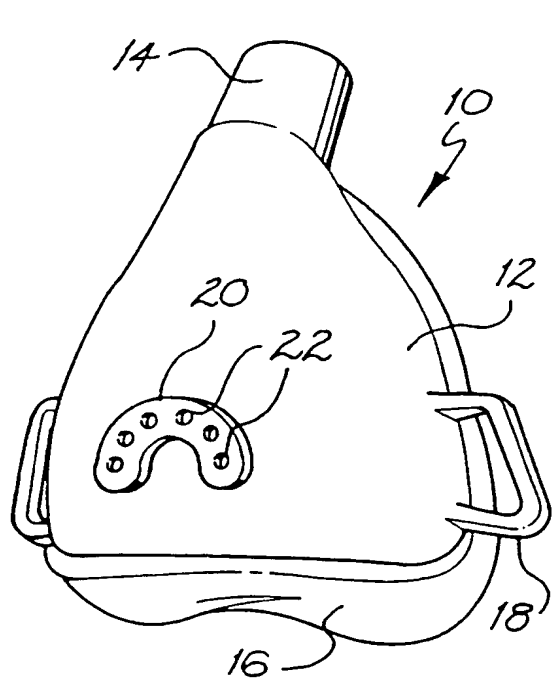


FIG. 3

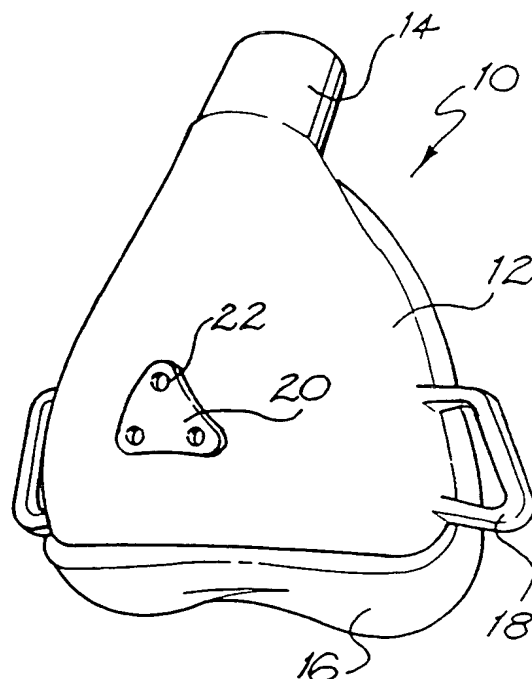


FIG. 4

2/4

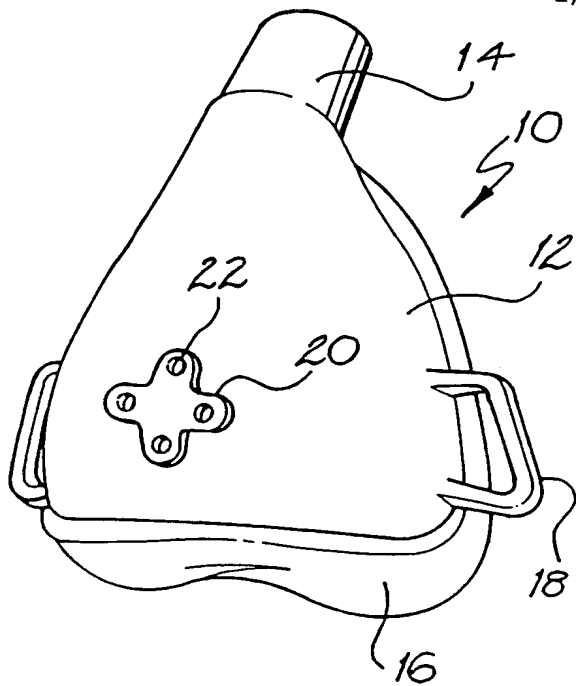


FIG. 5

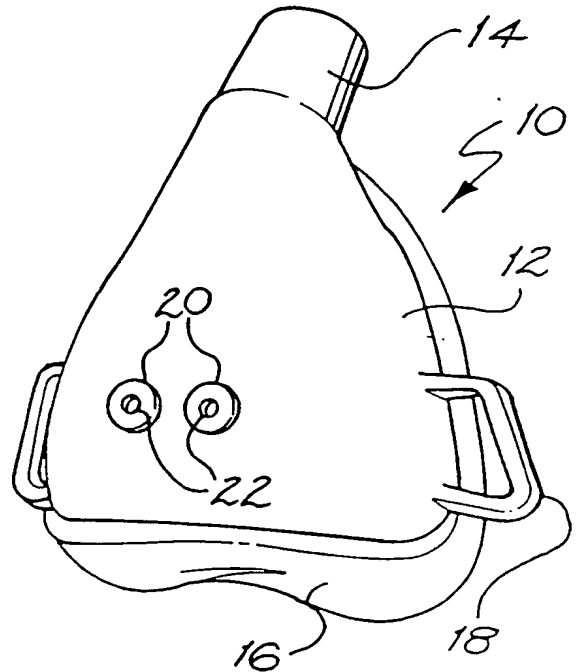


FIG. 6

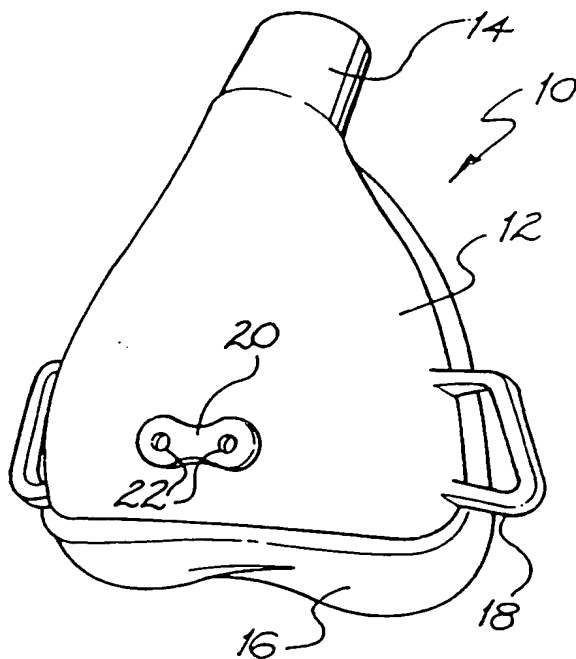


FIG. 7

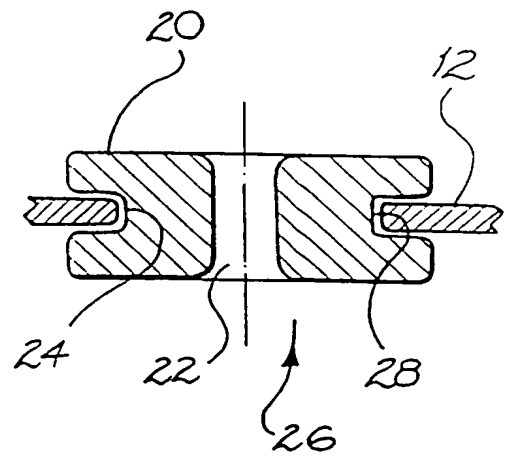
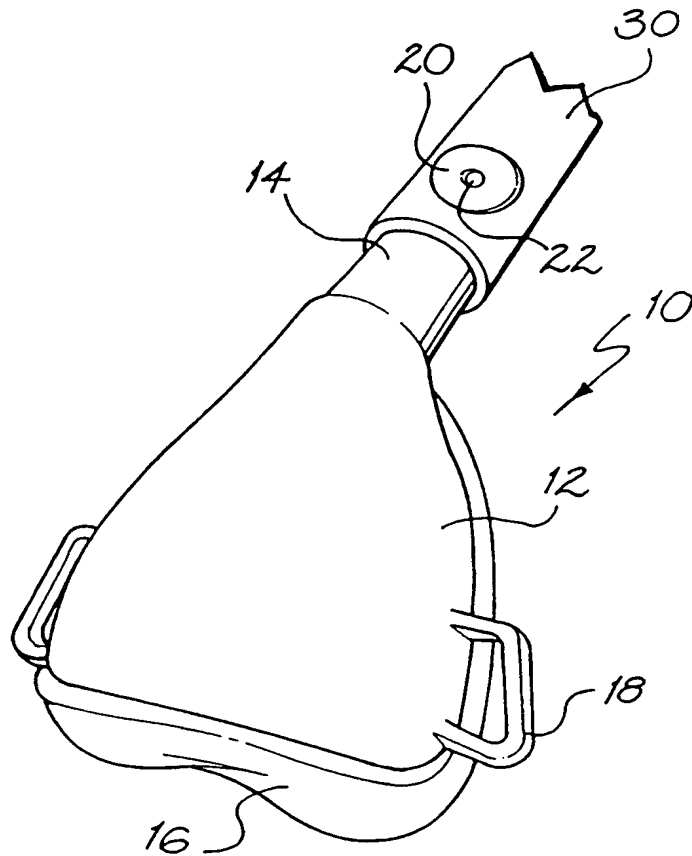
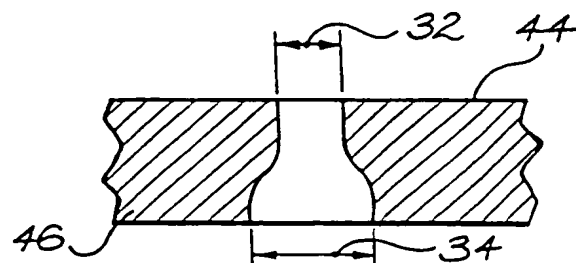
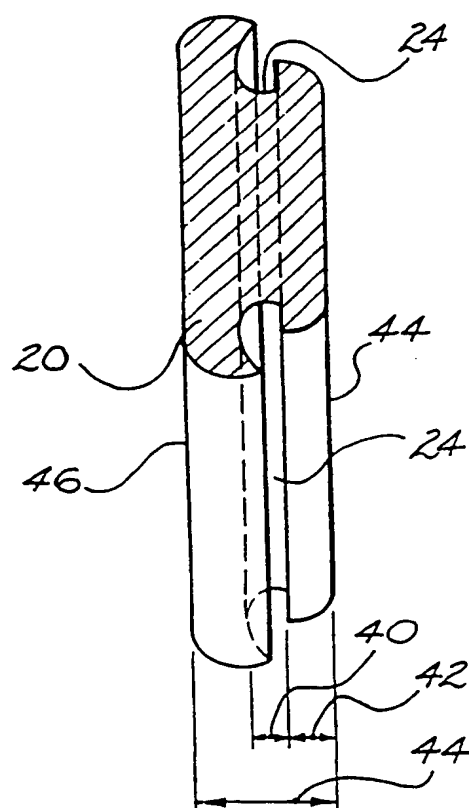
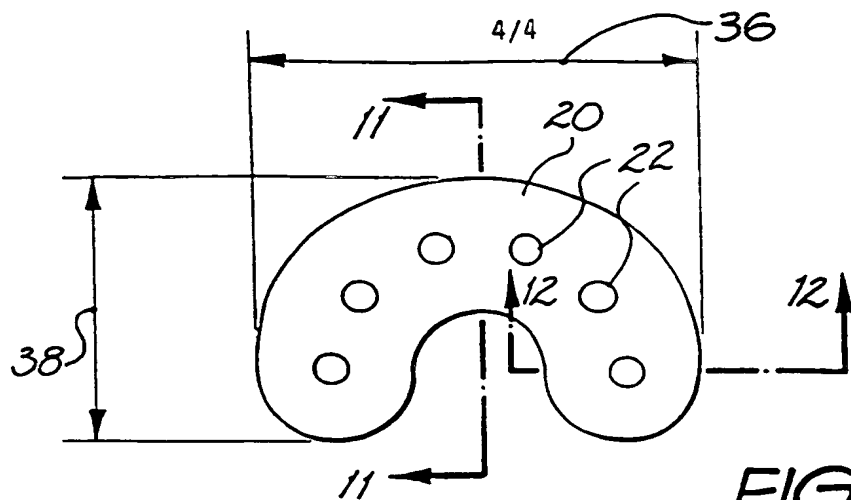


FIG. 8

*FIG. 9*





## INTERNATIONAL SEARCH REPORT

International Application No.

PCT/AU 98/00067

<b>A. CLASSIFICATION OF SUBJECT MATTER</b>												
Int Cl <sup>0</sup> : A61M 16/06; A62B 18/02												
According to International Patent Classification (IPC) or to both national classification and IPC												
<b>B. FIELDS SEARCHED</b>												
Minimum documentation searched (classification system followed by classification symbols) IPC: A61H; A61M; A61B; A62B												
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched AU IPC: as above												
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) DERWENT: mask: vent: orifac: outlet: flex: elast: JAPIO: mask: vent: orifac: outlet: flex: elast:												
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>												
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.										
X	GB 1395391 A (VICKERS LIMITED) 29 May 1975 Column 1, lines 41 to 43 and Figures	1,2,11										
X	CA 1039144 A (C R BARD, INC) 26 September 1978 Page 6 lines 2-3, 26-27	1,2,11										
A	US 5121745 A (ISRAEL) 16 June 1992											
A	AU 64058/86 (595840) B (PROTECTOR SAFETY LTD) 9 April 1987											
A	GB 2267648 A (MEL (AVIATION OXYGEN) LTD) 15 December 1993											
<input type="checkbox"/> Further documents are listed in the continuation of Box C <input checked="" type="checkbox"/> See patent family annex												
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Date of the actual completion of the international search 6 April 1998		Date of mailing of the international search report 17 APR 1998										
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200 WODEN ACT 2606 AUSTRALIA Facsimile No.: (02) 6285 3929		Authorized officer <i>D. Melhuish</i> DAVID MELHUISE Telephone No.: (02) 6283 2426										

### Information on patent family members

International Application No.

**PCT/AU 98/00067**

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Patent Document Cited in Search Report			Patent Family Member				
GB	1395391	NONE					
GB	2267648	AU	43423/93	EP	644787	GB	2281514
		US	5538001	WO	93/25275	ZA	9304039
US	5121745	NONE					
AU	64058/86	DK	2667/87	EP	276216	FI	881455
		NO	872182	WO	87/01950		
CA	1039144	NONE					